UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA
ALEXANDRIA DIVISION

GILDA HAGAN-BROWN Plaintiff, v. ELI LILLY AND COMPANY, an Indiana corporation, Defendant.	CASE NO.: 1:14-CV-01614
JANINE ALI Plaintiff, v. ELI LILLY AND COMPANY, an Indiana corporation, Defendant.	CASE NO.: 1:14-CV-01615

DEFENDANT'S MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION TO COMPEL

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PRELIMINARY STATEMENT

The issues in these two lawsuits are simple and straightforward: Plaintiffs allege that Lilly failed to provide an adequate warning of the risk of suffering adverse symptoms when stopping Cymbalta; Lilly believes that the Cymbalta label's multiple warnings about these symptoms and how to manage them were fully adequate, as one federal court has already found, *McDowell v. Eli Lilly & Co.*, --- F. Supp. 3d ---, 2014 WL 5801604 (S.D.N.Y. Nov. 7, 2014), *reconsideration denied*, 2015 WL 845720 (S.D.N.Y. Feb. 26, 2015), and that in any event, practicing physicians are well aware of the inherent risk of such symptoms when stopping an antidepressant like Cymbalta. The principal focus of discovery will thus be the treatment of the plaintiffs and their physicians' understanding of this risk when they decided to prescribe Cymbalta. Indeed, two federal courts have granted summary judgment for Lilly because the prescribers in those cases understood Cymbalta's risk of discontinuation symptoms and additional information in the label would not have altered their treatment decisions. *See Carnes v. Eli Lilly & Co.*, No. 0:13–591–CMC, 2013 WL 6622915, at *6-7 (D.S.C. Dec. 16, 2013); *McDowell*, 2014 WL 5801604, at *16-18.

While this lawsuit will therefore focus on these case-specific issues, the Plaintiffs nevertheless have the benefit of nearly three million pages of discovery from Lilly that has been collected and produced over the last two years in related cases. This discovery includes the central FDA regulatory submissions and correspondence for Cymbalta -- including clinical trial reports, labeling, promotional material, safety reports, and related FDA communications and submissions -- and more than 600,000 pages of emails from nine central Lilly employees who focused on Cymbalta. These productions took significant time and effort -- the emails alone involved the work of 170 reviewers and support staff at its peak, logging more than 12,700 hours. Indeed, when declining to centralize these and related lawsuits, the Judicial Panel on

Multidistrict Litigation specifically noted that Lilly's production "that has occurred to date has been substantial." *In re: Cymbalta (Duloxetine) Prods. Liab. Litig.*, No. MDL 2576, 2014 WL 7006713, at *1 (J.P.M.L. Dec. 10, 2014).

Against this backdrop, Plaintiffs' assertion in the current motion that they have somehow been deprived of an ability to litigate their cases here cannot withstand scrutiny. Plaintiffs have the Cymbalta regulatory documents in the industry-standard format (.tiff format with searchable text and corresponding load files) consistent with how they subsequently demanded electronic documents, but now ask Lilly to redo its regulatory file production at significant cost and with almost no marginal benefit (especially since Lilly did not convert to Electronic Common Technical Document ("eCTD") format for Cymbalta submission until 2007, three years after Cymbalta's first approval). Moreover, Plaintiffs have more than 600,000 pages of emails from key employees who worked on Cymbalta, but now ask that this process be repeated for (at least) 29 additional employees. Even if such massive additional discovery were appropriate, which it is not, such an immense additional document production would take tens of thousands of person-hours and months to complete, and thus could not possibly be completed within the discovery constraints in this District or the current scheduling order.

Finally, Lilly approached Plaintiffs' counsel to propose sharing the expenses of retaining a vendor to carry out records collection for these cases and the many other cases Plaintiffs' counsel have brought nationwide. The costs of record collection in pharmaceutical litigation are significant, and Lilly reasonably proposed sharing that cost with Plaintiffs' counsel, who after all have the initial obligation to investigate the claims of their clients, including through collection and review of medical records. Plaintiffs' counsel declined to participate, and Lilly proceeded to retain a vendor at significant cost. Plaintiffs now seek to free-ride on that cost and demand

copies of the records for a simple "copying fee." Lilly respectfully submits that such an outcome is not fair or equitable.

I. BACKGROUND ON LILLY'S PRIOR PRODUCTIONS

As Plaintiffs acknowledge (at 14), these two cases are part of a series of "nearly identical" claims filed around the country by three principal firms, including the California-based Baum Hedlund firm apparently taking the lead in these two lawsuits. As part of the first wave of these lawsuits, Lilly and Plaintiffs' counsel engaged in significant discovery, principally in two cases filed in April 2013 in the Central District of California, *Herrera* and *Hexum*.[1] In October 2013, Plaintiffs served Lilly with 167 requests for production and 19 interrogatories that ranged widely over every area of Lilly's functioning, requested information on medicines not at issue in the matter, including some not even manufactured by Lilly, and were otherwise exceptionally broad. Declaration of Jeffrey Bozman ("Bozman Decl."), Ex. A (Pls.' First Set of Requests for Production, *Hexum v. Eli Lilly & Co.* (Oct. 15, 2013)); Bozman Decl., Ex. B (Pls.' First Set of Interrogs., *Hexum v. Eli Lilly & Co.* (Oct. 15, 2013)). Lilly nevertheless made significant productions as outlined below.

Regulatory Files Production: First, Lilly responded with initial productions of its regulatory filings totaling 91,415 documents and 1,750,453 pages, which included the regulatory submission packages for the Investigational New Drug Application ("IND") application for

[1] *Hexum v. Eli Lilly & Co.*, No. 2:13-cv-2701-SVW (MAN) (C.D. Cal) and *Herrera v. Eli Lilly & Co.*, No. 2:13-cv-2702-SVW (MAN) (C.D. Cal.). A third case, *Carter v. Eli Lilly and Co.*, was filed in parallel with *Hexum* and *Herrera*. That case was voluntarily dismissed in September 2014 shortly after the deposition of the plaintiff. Joint Stip. of Voluntary Dismissal, *Carter v. Eli Lilly & Co.*, No. 2:13-cv-2700 GHK (FFM) (C.D. Cal. Sept. 12, 2014). Lilly made its initial productions in *Carnes v. Eli Lilly and Co.*, a case then pending in the United States District Court for the District of South Carolina, but the district court granted Lilly's motion for summary judgment shortly thereafter. *Carnes v. Eli Lilly & Co.*, No. 0:13–591–CMC, 2013 WL 6622915 (D.S.C. Dec. 16, 2013). Lilly's references herein to the production in *Hexum* and *Herrera* encompass the documents produced in *Carnes*.

Cymbalta and the New Drug Application ("NDA") for each Cymbalta indication. Declaration of Jennifer A. Holmes ("Holmes Decl.") at ¶ 4. The productions also included related supplements and amendments; supplemental reporting including Periodic Safety Updates Reports, adverse event reporting data, and risk management plans; correspondence with the FDA regarding draft and implemented labeling; copies of draft and final marketing and promotional materials; and clinical trial materials. Bozman Decl., Ex. C (Email from Phyllis A. Jones to T. Matthew Leckman (Dec. 9, 2013)). Lilly has since made supplemental update productions of regulatory material in August 2014, September 2014, and March 2015, totaling another 25,195 pages. Bozman Decl., Ex. D (production transmission emails).

Importantly, Plaintiffs' document requests in *Hexum* and *Herrera* did not request production of the regulatory files in any specific format--eCTD, native file, or otherwise--and Lilly therefore made the IND/NDA productions in .tiff format with accompanying load files, metadata, and searchable text, which, as Plaintiffs appear to acknowledge in their motion (at 12), reflects the standard production format for electronically stored information ("ESI") in commercial litigation. Indeed, Plaintiffs' counsel in *Hexum* and *Herrera* subsequently sent Lilly a draft stipulation, proposing that "Lilly will produce electronic documents ***in TIFF*** or native format of an electronic document by creating the file directly from the original electronic document" and that "[p]roper conversion of files . . . is acceptable if the process is defensible and documented." Bozman Decl., Ex. E (Draft ESI Protocol) at B(1) (emphasis added); *see also id.* (Email from T. Matthew Leckman to Phyllis A. Jones (July 1, 2014)). Lilly returned the draft stipulation with proposed changes in August 2014 and never heard back from Plaintiffs, despite following up on the matter in November 2014. *See* Bozman Decl., Ex. F (Emails from Phyllis A.

Jones to T. Matthew Leckman (Aug. 1, 2014; Nov. 3, 2014). No ESI stipulation was ever entered between the parties in these matters nor in the cases pending before this Court.

Rule 30(b)(6) Deposition Productions: Apart from the extensive regulatory files production, Lilly made three additional document productions in July 2014, in connection with three 30(b)(6) depositions noticed by Plaintiffs: for Drug Safety Surveillance, for Regulatory Affairs, and for Sales Training. Collectively, those notices included 31 document requests. *See* Bozman Decl., Ex. G (Amended Notice of Video Deposition Pursuant to Fed. R. Civ. P. 30(b)(6): Sales Training for Cymbalta, *Hexum* (June 18, 2014)); Bozman Decl., Ex. H (Amended Notice of Video Deposition Pursuant to Fed. R. Civ. P. 30(b)(6): Drug Safety Surveillance, *Hexum* (June 18, 2014)); Bozman Decl., Ex. I (Amended Notice of Video Deposition Pursuant to Fed. R. Civ. P. 30(b)(6): Regulatory Affairs, *Hexum* (June 18, 2014)). Lilly's productions in response to these requests totaled 12,002 pages. Holmes Decl. ¶ 7. Lilly also provided at Plaintiffs' request an index of its 30(b)(6) productions and its earlier productions to match the documents with particular discovery requests. *See* Bozman Decl., Ex. J (Email from Phyllis Jones to Kevin O'Brien (July 9, 2014)); Bozman Decl., Ex. K (Email from Phyllis Jones to T. Matthew Leckman (Aug. 6, 2014)).

Production of Key Employee Emails and Related Materials: Subsequent to these two large productions, the *Herrera*/*Hexum* plaintiffs served an additional 35 requests for production on Lilly in September 2014, well after counsel in those matters and counsel in this matter had begun jointly filing other cases related to Cymbalta discontinuation around the country. *See* Bozman Decl., Ex. L (Pls.' Second Set of Requests for Production, *Hexum* (Sept. 19, 2014)). Those requests included demands for the *entire* "custodial files" of 61 individuals and were made less than three months before the close of fact discovery. *Id.* In response, Lilly produced more

than an additional 600,000 pages of responsive emails of nine Lilly employees who had significant involvement with or responsibility for Cymbalta across company functions, as well as certain targeted sets of materials (like meeting minutes) responsive to Plaintiffs' supplemental requests. Because of the breadth of the requested documents, this review and production required a significant undertaking. Lilly engaged the services of approximately 170 document reviewers and support staff who have spent approximately 12,700 hours reviewing documents for this production. Holmes Decl. ¶ 8.

II. PLAINTIFFS' DISCOVERY REQUESTS IN THIS CASE

At the parties' Rule 16 conference on Wednesday, January 28, 2015, Plaintiffs' counsel confirmed he had access to Lilly's prior significant productions -- at one point defending his tardiness in submitting any additional requests due to the time needed to review Lilly's existing extensive production. Thereafter, rather than craft targeted requests to supplement the significant production to date, Plaintiffs' counsel basically started over by serving Lilly with 105 requests for production, 61 requests for admission, and numerous interrogatories.[2] (Pls.' Mot. to Compel, Exs. 1-A, 2-A, 3-A.) Many of these requests sought documents already contained in Lilly's extensive *Hexum* and *Herrera* production, and Lilly responded primarily to Plaintiffs' document requests by identifying the Bates numbers in its existing production where the responsive documents could be found. Some responses included additional indices identifying the hundreds or thousands of Bates ranges corresponding to documents responsive to a particular request. For

[2] Due to certain multi-part interrogatories, Lilly construed them as totaling 41, and objected on the grounds that they exceeded Rule 33's limit on the number of interrogatories. Nonetheless, Lilly objected and/or responded to each individual interrogatory.

some document requests that had not been covered in the prior production, Lilly has agreed to produce (and indeed has begun producing) responsive documents.[3]

On March 13, 2015, Plaintiffs' counsel sent Lilly three letters claiming deficiencies in Lilly's responses to Plaintiffs' requests for production, requests for admission, and interrogatories. (Pls.' Mot. to Compel, Ex. 7). On March 17, 2015, the parties held a lengthy telephonic meet-and-confer on these issues and were able to come to a resolution on numerous issues. Some areas of resolution included Lilly's agreement to collect emails from two additional custodians (which is underway) and Lilly's production of several documents in Excel format to facilitate Plaintiffs' review. (*See* Pls. Mot. to Compel, Ex. 9 (Lilly's Resp. to Pl.'s Discovery Letters (Mar. 19, 2015).) After clarifying some of Plaintiffs' broad demands on other issues, Lilly also agreed to additional searches and production of documents, including identification of additional names of employees, identification of certain vendors used for Cymbalta activities, and a search for additional "brand plans" for Cymbalta. *Id.*

Finally, as noted above, shortly after the JPML declined to centralize these cases, Lilly proposed that the parties together engage a vendor to gather medical records and to share in the significant cost of their collection. *See* Bozman Decl., Ex. M (Letter from Phyllis A. Jones to Counsel (Jan. 13, 2015)) at 2. Collecting medical records from various doctors and health care facilities can require significant effort and expense in a pharmaceutical products liability action. Parties typically engage a vendor to locate and collect these records, which can be scattered among different sources. Plaintiffs' counsel rejected this proposal, instead suggesting to have full access to the records collected by Lilly while paying only the nominal cost of copying the

[3] For example, Lilly has produced foreign labeling responsive to RFP No. 22, publication plans responsive to RFP No. 48, market research responsive to RFP No. 80, and documents relating to certain physicians responsive to RFPs Nos. 88, and 90.

records once collected, but not contributing to the substantial collection costs. *See* Bozman Decl., Ex. N (Letter from Michael L. Baum, at al. to Phyllis A. Jones and Mike X. Imbroscio (Jan. 22, 2015)) at 3. Lilly went forward with its collection of medical records in order to diligently investigate its case, seeking individual authorization from Plaintiffs for each medical provider or facility it accessed, as requested by Plaintiffs' counsel. Lilly also gave Plaintiffs' counsel the opportunity to edit the authorization form to limit it temporally or by subject matter in order to address any concerns about its scope, but Plaintiffs' counsel provided no edits or restrictions. *See* Bozman Decl., Ex. O (Letter from Phyllis A. Jones to R. Brent Wisner (Jan. 27, 2015)) at 2; Bozman Decl., Ex. P (Letter from Phyllis A. Jones to R. Brent Wisner (Feb. 5, 2015)) at 2. Plaintiffs here now seek to obtain the records Lilly has collected (or is in the process of collecting) for these two plaintiffs, offering only the nominal copying fee.

ARGUMENT

I. Plaintiffs Are Not Entitled to Previously Produced Documents in a Different Format (RFP No. 1).

Plaintiffs ask that Lilly re-produce documents that were part of Lilly's Cymbalta regulatory submissions to FDA in eCTD format, even though Lilly has already produced these documents in another suitable form. Plaintiffs' request is not warranted under the rules, nor would it make any practical sense to go through such a burdensome exercise that would yield little marginal benefit.

Under the express terms of Rule 34(b) "[a] party need not produce the same electronically stored information in more than one form." Fed. R. Civ. P. 34(b)(E)(iii). As one court bluntly put it, if a party "ha[s] already received the document in another form, [it] may be out of luck." *Aguilar v. Immigration & Customs Enforcement Div. of U.S. Dep't of Homeland Sec.*, 255 F.R.D. 350, 357 (S.D.N.Y. 2008) (alterations in original); *see also Autotech Techs. Ltd.*

P'ship v. Automationdirect.com, Inc., 248 F.R.D. 556, 559 (N.D. Ill. 2008) ("It seems a little late to ask for [native files] after documents responsive to a request have been produced in both paper and electronic format.").

Lilly has already made its production of its Cymbalta regulatory submissions to FDA (i.e., the IND/NDA documents). Lilly objected to Plaintiffs' request for these documents again in eCTD format in part on the grounds that it "seeks documents previously produced by Lilly in productions to which Plaintiff has access." (Pls.' Mot. to Compel, Ex. 1-B (Lilly's Obj. to Pls.' First Set of Requests for Production) No. 1.) In its response, Lilly identified the corresponding Bates numbers to this prior production. (*See* Pls.' Mot. to Compel, Ex. 1-C (Lilly's Resp. to Pls.' First Set of Requests for Production) No. 1.) Lilly also objected to Instruction No. 11 in Plaintiffs' RFPs, which requested that all documents be produced in native format, conflicting with Rule 34(b)'s clear statement that parties are not obligated to make duplicate productions in different forms. (Pls.' Mot. to Compel, Ex. 1-B at 2.) Having already received the IND/NDA documents in one acceptable form, Plaintiffs are "simply too late" to request "a more particularized format," *In re Jemsek Clinic, P.A.*, No. 06-31766, 2013 WL 3994663, at *7 (Bankr. W.D.N.C. Aug. 2, 2013). The request is all the more out of place in these two lawsuits given this Court's emphasis on speed and targeted discovery.

Rule 34(b) also instructs that "[i]f a request does not specify a form for producing electronically stored information, a party must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form." Fed. R. Civ. P. 34(b)(2)(E)(ii). The reasonableness of the produced form depends "heavily upon the defendant's failure to ask for [a specific form] at the outset." *Aguilar*, 255 F.R.D. at 357. Such was the case at the time of Lilly's initial IND/NDA production. Plaintiffs' counsel only later initiated discussion about the

format of ESI production, but even then agreed that a .tiff production would be perfectly appropriate.

Plaintiffs do not seriously dispute that productions in .tiff format are widely accepted as a reasonably usable form of data. *See In re Jemsek Clinic, P.A.*, 2013 WL 3994663, at *7 ("Use of TIFF images is a 'reasonably usable form' for the production of ESI under Rule 34(b)(2)(E) when the parties have never discussed a particular format for production of electronic documents."); *cf. Branhaven, LLC v. BeefTek,* Inc., 288 F.R.D. 386, 392 (D. Md. 2013) ("[W]ithout Bates stamping and .tiff format, the data was not reasonably usable and therefore was insufficient under Rule 34."). Indeed, some court rules have adopted .tiff files as the default production format. *See Wyeth v. Impax Labs., Inc.*, 248 F.R.D. 169, 171 (D. Del. 2006) ("Paragraph 6 [of the district's Default Standard for Discovery of Electronic Documents] directs parties to produce electronic documents as image files (e.g. PDF or TIFF) if they cannot agree on a different format for production."). Courts in many mass product liability actions have also ordered production in .tiff format. *See, e.g., In re Am. Med. Sys., Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, MDL No. 2325 (S.D. W. Va.); *In re Celexa & Lexapro Prods. Liab. Litig.*, MDL No. 1736 (E.D. Mo.); *In re Prempro Liab. Litig.*, MDL No. 1507 (E.D. Ark.); *In re Chantix Prods. Liab. Litig.*, MDL No. 2092 (N.D. Ala.); *In re Zoloft Prods. Liab. Litig.*, MDL No. 2342 (E.D. Pa.); *In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig.*, MDL 2226 (E.D. Ky.); *In re Bextra & Celebrex Marketing Sales & Prods. Liab. Litig.*, MDL 1699 (N.D. Cal.); *In re Nuvaring Prods. Liab. Litig.*, No. 4:08-MD-01964 (E.D. Mo.).

Files in .tiff format have many benefits, including the ability to be redacted, marked with confidentiality designations, and Bates stamped to ease tracking and use in document-heavy litigation. Once produced and loaded into a document review platform, they are text searchable

and sortable, but unlike native files, they do not run the risk of being altered, inadvertently or otherwise. Holmes Decl. ¶ 4. Plaintiffs read into Rule 34 a requirement that Lilly produce ESI with dynamic user capabilities such as internal hyperlinks and .html browsing. Lilly does not deny that these high tech features might marginally increase user functionality, but that is not the standard of Rule 34. Because Lilly has already produced IND/NDA documents in a reasonably usable .tiff format, it has complied with its discovery obligations under Rule 34, and Lilly should not be obligated to redo its production in this additional format at considerable expense.

Furthermore, much of the production about which Plaintiffs complain *cannot* be provided in an eCTD format. Because Lilly only began submitting documents to FDA in eCTD format in May 2007, the IND/NDA files prior to that date are not even in eCTD format. Holmes Decl. ¶ 3. The majority of the IND/NDA collection -- 54,348 of 91,415 IND/NDA documents -- predates this format changeover, and Lilly maintains these records in PDF or paper files.[4] *Id.* ¶ 5. This includes NDAs submitted for indications before 2007 and the IND, the pre-clinical development of the drug. Plaintiffs' claims here and in other similar cases focus on the adequacy of the warning about discontinuation-emergent adverse events in Cymbalta's label, which was initially issued in 2004 and has remained largely unchanged since. Plaintiffs allegations of inadequacy rely heavily on clinical trial data summarized in a 2005 medical journal article by Lilly scientist, Dr. David Perahia. (*See* Compl. ¶¶ 21-22.) Documents most pertinent to Plaintiffs' claims, such as the clinical trial reports and correspondence between Lilly and FDA about the development of the initial U.S. label, are part of the IND/NDA collection that does not exist in eCTD format. As a result, even a production of the native eCTD files that Plaintiffs seek will make little

[4] Post-2007 submission packages to FDA still include some e-files, PDFs, and Word documents as well. Holmes Decl. ¶ 2.

meaningful difference to justify the burden of re-production, the cost of which Plaintiffs have made no offer to share.

II. Plaintiffs' Proposed Discovery from Dozens of Additional Lilly Custodians Expands the Breadth of Discovery Beyond the Needs of These Cases.

Seeking discovery of emails from 29 additional individuals (or the 135 individuals on Plaintiffs' wish-list) cannot reasonably be justified under the Federal Rules. At a time when federal courts are contemplating ways to limit the number of document custodians even in complex commercial civil litigation, and when the Federal Rules of Civil Procedure are being specifically amended to encourage reasonableness and proportionality in electronic discovery, seeking discovery from 135 custodians is a ludicrous proposal. *See* Order Regarding E-Discovery, *DGC Sys., Inc. v. Checkpoint Techs., LLC*, No. 5:11-cv-03792-PSG, slip op. at 2 (N.D. Cal.) (ECF No. 33) (limiting email production requests to fifteen custodians); Model Order Regarding E-Discovery in Patent Cases, slip op. at 3 (Fed. Cir.) (limiting email production requests to five custodians); Summary of the Report of the Judicial Conference Committee on Rules of Practice and Procedure at App. B-5-8 (Sept. 2014), *available at* http://www.uscourts.gov/uscourts/RulesAndPolicies/rules/Reports/ST09-2014.pdf.

Even Plaintiffs' "culled" list of 29 additional custodians here ignores the enormous burden that such collection and review efforts would present. Taking the first nine custodians as an average, Plaintiffs are proposing an exercise that would require nearly 40,000 hours of reviewer time, where a legion of reviewers would be have to review tens if not hundreds of thousands of emails ensnared in the broad search terms for responsiveness, privilege, confidential patient information, and proprietary information about other Lilly products. For foreign employees, there would be the added barrier of complying with foreign data protection

laws limiting the ability of companies to provide identifying information about the foreign employees themselves.[5]

The cost to comply with even the 29 custodians would be astronomical. Assuming 40,000 hours of project time at a relatively low average reviewer rate of only $50/hour, the enterprise would cost Lilly upwards of $2 million. For two cases where the damages claimed, even in the light most favorable to Plaintiffs, were transient and not life-threatening or otherwise permanently debilitating, such a cost is not reasonably proportional to the needs of this case.[6]

Courts have the power to limit discovery based on the principle of proportionality in Rule 26(b) if "the discovery sought is unreasonably cumulative or duplicative, or can be obtained from some other source that is more convenient, less burdensome, or less expensive" or if "the burden or expense of the proposed discovery outweighs its likely benefit, considering the needs of the case, the amount in controversy, the parties' resources, the importance of the issues at stake in the action, and the importance of the discovery in resolving the issues." Fed. R. Civ. P. 26(b)(2)(C)(iii). In their discretion, courts can ensure "the scope and duration of discovery is reasonably proportional to the value of the requested information, the needs of the case, and the parties' resources." *Chen-Oster v. Goldman, Sachs & Co.*, 285 F.R.D. 294, 303 (S.D.N.Y. 2012) (quoting The Sedona Conference Commentary on Proportionality in Electronic Discovery, 11 Sedona Conf. J. 289, 294 (2010)).

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[5] At least three of the individuals on Plaintiffs' list of 29 are foreign employees, and of the full list of 135 proposed custodians, at least 17 appear to be located outside of the United States. Given that this is a dispute about U.S. citizens who were prescribed Cymbalta in the United States by U.S. physicians based on the U.S. FDA-approved labeling, one can seriously question the need to collect such information from tangential foreign witnesses.

[6] Plaintiffs allege that they suffered discontinuation symptoms such as anxiety, panic attacks, insomnia, nightmares, out-of-body experiences, crying uncontrollably, buzzing in the head, mood swings, dizziness, glazed eyes, dry mouth, and sweating. (Compl. ¶ 33.)

Given the extensive production already available to Plaintiffs, which itself has been quite costly to Lilly, it is difficult to justify another massive production when the additional information is neither necessary to the prosecution of the claims nor likely to materially change the picture presented by the existing productions. Plaintiffs already have access to the emails related to Cymbalta discontinuation from nine Lilly custodians who were selected because they were deeply involved with the drug. As categorized below, these employees collectively span the medicine's entire life cycle and cover the major aspects of the product: clinical research, labeling, regulatory, marketing, and safety:

- David Perahia -- European Regional Physician (involved in Cymbalta clinical trials). Bozman Decl., Ex. Q (Perahia Dep.) at 20:2-22:15.
- Nayan Acharya -- Senior Medical Director, Global Patient Safety (safety physician for Cymbalta). Bozman Decl., Ex. T (Hoog Dep.) at 215:13-216:6.
- Mark Bangs -- Safety Physician (primary responsibility for Cymbalta safety surveillance). Bozman Decl., Ex. R (Knowles 30(b)(6) Dep. Ex 2).
- Greg Brophy -- Director, U.S. Regulatory Affairs. Bozman Decl., Ex. S (NDA Submission Cover Letter) at CYM-00725747.
- Sharon Hoog -- Medical Advisor, Regulatory Affairs (liaison to FDA for Cymbalta regulatory submissions). Hoog Dep. at 17:15-19:18
- Bryan Boggs -- Manager, U.S. Regulatory Affairs. Bozman Decl., Ex. U (sNDA Submission Cover Letter) at CYM-00978617
- Ann Sakai-Robbins -- Associate Director, U.S. Regulatory Affairs (liaison to FDA for Cymbalta regulatory submissions). Bozman Decl., Ex. V (sNDA Submission Cover Letter) at CYM-00944957
- John Hixon -- Cymbalta Brand Team Leader. Bozman Decl., Ex. W (Musleh Dep. Ex. 2)
- Sara Mescher -- Regulatory Labeling Consultant. Bozman Decl., Ex. X (Mescher Dep.) at 12:22-25.

Plaintiffs' request demonstrates a fundamental misunderstanding of Lilly's structure. At Lilly, employees are often organized by function and their duties cut across multiple medicines; thus, the development and marketing of a product over the course of a decade draws upon the skills of a multitude of employees in various departments and capacities. As a result, hundreds

of employees' work has intersected with Cymbalta to some degree but frequently without sustained involvement. Moreover, many emails of employees with only brief or intermittent involvement with Cymbalta would be captured in correspondence with more central Cymbalta employees, such as the nine custodians, who frequently interfaced with others in the company about Cymbalta. For example, Sharon Hoog, and later Ann Sakai-Robbins, served as the regulatory point of contact for communication between the company and FDA on Cymbalta matters; Dr. Perahia was a central employee on clinical trials, and Drs. Bangs and Acharya were the point persons on drug safety. Taken together, these nine employees were central to Cymbalta, and at least one of them is likely to be copied in virtually every piece of meaningful Cymbalta email correspondence. Plaintiffs thus already have access to substantial internal communications regarding Cymbalta, as evidenced by their extensive use of internal emails in the company depositions already taken and from the extensive exhibit list Plaintiffs have prepared in the *Hexum* and *Herrera* matters.

Plaintiffs provide no reason why the emails sought from its designated "Tier One" individuals -- or any of the list of 135 -- are important enough to justify the burden and time required for the additional collection beyond the bald assertion that these individuals "likely have relevant emails about Cymbalta withdrawal." (Pl.'s Mot. to Compel at 13-15.) As for the list of 29 that are the subject of this motion, some identified have only minimal discoverable information. For example, Angela Wade is a Lilly in-house counsel who was involved in reviewing Prozac marketing materials in the mid-1990s, about a decade before Cymbalta was even launched. Hoog Dep. at 142:12-149:7. Her emails would contain substantial privileged material and have little discoverable Cymbalta material. (Indeed, it appears that three individuals on Plaintiffs list of 135 are lawyers.) The relevant emails of other individuals listed

by Plaintiffs would also likely add little additional information to that already uncovered through document production and deposition. For example, Daniel K. Kajdasz (who left Lilly in 2008) and Durisala Desaiah were the statistician and medical writer, respectively, who provided assistance on the 2005 article for which Dr. Perahia was the lead author. Perahia Dep. at 146:13-147:16. Dr. Perahia's emails have been produced to Plaintiffs, and many show that Mr. Kajdasz and Dr. Desaiah were copied on the various exchanges about the 2005 article. Given that Plaintiffs have these emails, and that Dr. Perahia has already been deposed extensively about the article, there is little additional benefit to gain to justify the burden of separately collecting and reviewing from emails from Mr. Kajdasz and Dr. Desaiah.

Plaintiffs' motion also reveals her misplaced reliance on European labeling in a case about U.S. product information, an approach already rejected by Judge Sweet in *McDowell v. Eli Lilly*. In denying Plaintiffs' motion for reconsideration of summary judgment for Lilly, the court reasoned that "[t]he mere existence of a differently structured and written European label does not establish that the U.S. label is insufficient, misleading, or legally inadequate." *McDowell v. Eli Lilly & Co.*, No. 13-CV-3786, 2015 WL 845720, at *5 (S.D.N.Y. Feb. 26, 2015). Discovery with a non-U.S. focus has little value, including from employees located outside the United States such as Joel Raskin and Marcia Vowles. Individuals who worked primarily on non-U.S. matters will have little information in their email accounts about Cymbalta's U.S. label or the FDA regulatory process. Moreover, because "evidence concerning other countries' regulatory policies may confuse and mislead the jury," *Tyree v. Boston Scientific Corp.*, No. 2:12-CV-08633, 2014 WL 5445769, at *4 (S.D.W. Va. Oct. 22, 2014), courts often exclude foreign labeling and other regulatory evidence in failure-to-warn cases, *see, e.g., In re Seroquel Prods. Liab. Litig.*, 601 F. Supp. 2d 1313, 1318 (M.D. Fla. 2009); *In re Viagra Prods. Liab. Litig.*, 658

F. Supp. 2d 950, 965 (D. Minn. 2009). The Sixth Circuit also recognized the limited importance of a medicine's foreign labeling, finding that the allegedly "more detailed instructions" contained in the medicine's European label did not "create[] a triable issue of fact." *Meridia Prods. Liab. Litig. v. Abbott Labs.*, 447 F.3d 861, 867 (6th Cir. 2006). Thus, the information Plaintiffs seek from non-U.S. employees among its 29 custodians is not reasonably calculated to lead to the discovery of admissible evidence due to its strong chance of being factually irrelevant and excluded at trial. *See* Fed. R. Civ. P. 26(b).

Perhaps cognizant that these two lawsuits could not conceivably support the additional substantial discovery envisioned by their motion, Plaintiffs seek to justify their requests by pointing to the other Cymbalta actions pending across the country. But the kind of all-inclusive mass-tort discovery contemplated by Plaintiffs' motion is fundamentally inconsistent with the scheduling order in these two cases. Such discovery -- which Lilly maintains is not appropriate in this litigation regardless of the number of Plaintiffs -- typically takes place over period of a year to 18 months, not the roughly six weeks left for discovery in these two actions. To be sure, any additional discovery provided in these cases will be available for use in the other cases -- for instance, additional documents being produced in response to the requests in these cases and any deposition testimony taken in connection with the multiple company deposition notices Plaintiffs have now served. But Plaintiffs cannot use these cases as a vehicle to conduct such all-encompassing discovery if only for the practical fact that it could never be accomplished within the current timelines. Plaintiffs have more than adequate information to present their cases, and additional email production should be denied.

III. Plaintiffs are Not Entitled to Free Ride on Lilly's Discovery Work (RFP No. 96)

Plaintiffs' request for copies of medical records Lilly has expended significant resources to obtain boils down to money. Plaintiffs made the conscious choice not to join Lilly in

engaging a vendor to collect medical records, thus avoiding sharing the substantial expenses for such services, but now they seek to obtain copies of those records for only a nominal copying fee. Such an outcome is not fair, and ignores Plaintiffs' independent obligation to conduct such discovery and not simply free ride on Lilly's effort. *See Hann v. Michigan*, No. 05–71347, 2009 WL 2929770 (E.D. Mich. Sept. 3, 2009) ("Defendants do not have to produce Plaintiff's medical records that Defendants' counsel has in its possession. Plaintiff must conduct his own discovery."); *Singleton v. Hedgepath*, No. 1:08-CV-00095-AWI, 2011 WL 1806515, at *8 (E.D. Cal. May 10, 2011) (declining to "order Defendants to produce documents that are equally accessible to both parties" just "so that Plaintiff can avoid costs."). Such a request seems especially incongruous given that, in the same motion, Plaintiffs seek to impose on Lilly millions of dollars of additional discovery expenses to collect and process dozens more email custodians.

To be clear, Lilly would have no objection to providing copies of all of the records it obtains were Plaintiffs to compensate Lilly for a share of the retrieval expenses beyond copying fees. Indeed, if the concern is that Plaintiffs do not want to share in the collection of records from medical and other provides Plaintiffs deem as tangential, certainly the parties could work through such a protocol, especially since Plaintiffs are demanding the right to approve every additional authorization as new providers are identified. But the outright refusal to share in any expenses -- even for the most relevant providers like the prescribing physicians -- warrants little sympathy.

CONCLUSION

For the foregoing reasons, Lilly respectfully requests that the Court deny Plaintiffs' Motion to Compel in its entirety.

DATED this 1st day of April, 2015.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on the 1st day of April, 2015, I will electronically file the foregoing with the Clerk of Court using the CM/ECF system, which will then send a notification of such filing (NEF) to the following:

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